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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/196,867	11/20/98	KELSALL	B 14014.0312

HM12/0917

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EXAMINER	
DECLOUX,A	
ART UNIT	**PAPER NUMBER**
1644	6

DATE MAILED: 09/17/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/196,867	Applicant(s) Kelsall et al
	Examiner Amy DeCloux	Group Art Unit 1644

☐ Responsive to communication(s) filed on _____ .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-13* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-13* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. The examiner of your application in the PTO has changed.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-11, drawn to a method of downregulating IL-12 with CR3/4 ligands, classified in class 514, subclass 2, and class 424, subclass 130.1, or

II. Claim 12, drawn to a method of screening a substance for its ability to down regulate IL-12 upon binding CR3, classified in class 435, subclass 7.1, or

III. Claim 13, drawn to a method of screening a substance for its ability to down regulate IL-12 upon binding CR4, classified in class 435, subclass 7.1.

3. Inventions I, II and III are different methods. These inventions require different ingredients, process steps and endpoints. Invention I is a method of downregulating IL-12, while methods II and III are methods of screening for substances able to downregulate IL-12. Methods II and III are distinct because in Invention II the method of screening of a substance for its ability to down regulate IL-12 is upon the binding of CR3, while in Invention III it is upon the binding of CR4. Therefore, they are patentably distinct.

4. Because these inventions are distinct for the reasons given above and the search required for each Invention is not required for the other and because each Invention has acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

5. This application contains claims directed to the following patentably distinct species of the claimed Invention I. If Invention I is elected then a species election is required from any one of the following symptoms characteristic of autoimmune disease;

A. Fever,
B. Fatigue,
C. Weight loss,
D. Joint swelling,
E. Pain,
F. Tenderness,
G. Stiffness, or
H. Skin lesions.

These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints. Therefore they are patentably distinct species in view of each other. Applicant is required to elect a single disclosed species, even though this requirement is traversed.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 3 is generic, for example.

6. Alternatively to the election of Species in Section 5, if Invention I is elected then a species election is required from any one of the following IL-12 induced Inflammatory responses of;

A. Autoimmune symptoms and diseases,
B. Inflammatory Bowel Diseases,
C. Sepsis.

These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints. Therefore they are patentably distinct species in view of each other. Applicant is required to elect a single disclosed species, even though this requirement is traversed.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently claim 5 is generic, for example.

7. If Invention I is elected then, and species A of section 6 is elected, then a sub-species election is required from any one of the following autoimmune diseases,

A. Multiple sclerosis,
B. Rheumatoid arthritis,
C. Diabetes mellitus,
D. Pernicious anemia,
E. Autoimmune gastritis,
F. Psoriasis,
G. Bechet's disease,
H. Idiopathic thrombocytopenic purpura,
I. Wegener's granulomatosis,
J. Autoimmune thyroiditis,
K. Autoimmune oophoritis,
L. Bullouspemphigoid,
M. Pemphigus,
N. Polyendocrinopathies,
O. Still's Disease,
P. Lambert-Eaton myasthenia syndrome,
Q. Myasthenia gravis,
R. Goodposture's Syndrome,
S. Autoimmne orchitis,
T. Autoimmune uveitis,
U. Systemic lupus erythematosus,
V. Sjorgren's Syndrome,
W. Ankylosing spondylitis,

These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints. Therefore they are patentably distinct species in view of each other. Applicant is required to elect a single disclosed species, even though this requirement is traversed.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 6 is generic, for example.

8. If Invention I is elected then, in addition to sections 5-7 above, a species election is required from any one of the following complement receptors;

A. CR3 or
B. CR4

These species are distinct because their structures and modes of action are different. Therefore they are patentably distinct species in view of each other. Applicant is required to elect a single disclosed species, even though this requirement is traversed.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic, for exmple.

9. If Invention I is elected and species A of Section 8 is elected, then, in addition to sections 5-7 above, a sub-species election is required from antibodies to any one of the following;

A. Complement receptor 3
B. IC3b,
C. ICAM-1,
D. Fibrinogen,
E. B-glucan,
F. C3b,
G. ICAM-2
H. ICAM-3,
I. A complement receptor 3-binding microorganism, or
J. A complement receptor 3-binding product of a complement receptor 3-binding microorganism.

These species are distinct because their structures and modes of action are different. Therefore they are patentably distinct species in view of each other. Applicant is required to elect a single disclosed species, even though this requirement is traversed.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 10 is generic, for example.

10. If Invention I is elected and species B of Section 8 is elected, then, in addition to sections 5-7 above, a sub-species election is required from antibodies to any one of the following;

A. Complement receptor 4
B. IC3b,
C. ICAM-1,
D. Fibrinogen,
E. B-glucan,
F. LPS
G. A complement receptor 4-binding microorganism, or
H. A complement receptor 4-binding product of a complement receptor 3-binding microorganism.

These species are distinct because their structures and modes of action are different. Therefore they are patentably distinct species in view of each other. Applicant is required to elect a single disclosed species, even though this requirement is traversed.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 11 is generic, for example.

11. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

12. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

13. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

14. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

15. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Serial No. 09/196867
Art Unit 1644

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Group 1644
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September 13, 1999

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9/15/99